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10/580,533	05/25/2006	Hirokazu Asaka	983.46174X00	5717

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EXAMINER	
FARDANESH, MARJAN	
ART UNIT	PAPER NUMBER
4123	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,533	ASAKA, HIROKAZU	
	Examiner	Art Unit	
	MARJAN FARDANESH	4123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/08/2010, 05,25,2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 2, 8-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Yamashita USPN 6,611,698 (cited by applicant).

With respect to claim 1, Yamashita discloses an optical measurement apparatus for living body comprising a measurement channel including an irradiation use optical fiber which is set at an irradiation position on a body surface in an inspection area of a subject and irradiates an inspection light having a predetermined frequency of from visible to near infrared range (Col. 6 lines 6-17, lines 36-39), and a light receiving use optical fiber which is set at a light receiving portion adjacent the irradiation use optical fiber on the body surface in the inspection area and receives the inspection light irradiated from the adjacent irradiation use optical fiber and penetrated through inside the subject(Col.6 lines 42-51), a light detection unit which detects the amount of inspection light received by the light receiving use optical fiber in an electrical signal(Col.7 lines 30-34), and a signal calculation and processing unit including a hemoglobin signal calculating unit which calculates a hemoglobin signal representing a hemoglobin concentration inside the subject through which the inspection light

has penetrated based on the electrical signal detected by the light detection unit (Col.8 line 63-Col.9 line 5), and an optical fiber setting adequacy evaluation unit (Figure 1, Element 17) which evaluates adequacy of setting on the body surface in the inspection area of the irradiation use optical fiber or the light receiving use optical fiber both of which constitute the measurement channel, characterized in that the signal calculation and processing unit further includes a pulse wave calculation unit which calculates an intensity of a pulse wave component due to heartbeats of the subject contained in the hemoglobin signal calculated by the hemoglobin signal calculation unit, and the optical fiber setting adequacy evaluation unit evaluates adequacy of setting on the body surface of the subject of the irradiation use optical fiber or the light receiving use optical fiber based on the intensity of the pulse wave component calculated by the pulse wave calculation unit(Col.8 lines 63-67, Col.9 lines 20-67).

With respect to claim 2, a plurality of the measurement channels are included and are constituted by a plurality of the irradiation use optical fibers and a plurality of the light receiving use optical fibers (Figure1, Elements 8-1 to 8-4 and 10-1 to10-5, Col.6 lines 57-61, Col. 7 lines 14-26).

With respect to claims 8/1,8/2, 9, the optical fiber setting adequacy evaluation unit evaluates the setting adequacy of the irradiation use optical fiber and/or the light receiving use optical fiber on the body surface of the subject based on whether

the intensity of the pulse wave component calculated is larger than or smaller than the predetermined threshold value , also characterized in that further comprises means for inputting the predetermined threshold value for the intensity of the pulse wave component by an operator (Col.9 lines 24-Col.10 line 23).

With respect to claim 10/1,10/2, the calculation of the intensity of the pulse wave component by the pulse wave calculation unit and the evaluation of the setting adequacy of the irradiation use optical fibers and/or the light receiving use optical fibers for the respective measurement channels based on the calculation by the optical fiber setting adequacy evaluation unit are performed during a preparatory measurement prior to an actual optical measurement for the living body(Col.9 lines 13-17) and a resetting is performed for an irradiation use optical fiber and/or a light receiving use optical fiber of a measurement channel of which setting is evaluated inadequate by the optical fiber setting adequacy evaluation unit(Col.9 lines 32-49).

With respect to claim 11/1,11/2, means for rejecting after the actual measurement a hemoglobin signal for obtaining living body information inside the living body of a measurement channel for which resetting of the irradiation use optical fiber or light receiving use optical fiber on the body surface has been performed is evaluated inadequate regardless to the performance of the resetting of the

irradiation use optical fiber or light receiving use optical fiber(Col.10 lines 34-Col.12 line 67, Fig7,8)

With respect to claim12/1,12/2, the evaluation of the setting adequacy of the irradiation use optical fiber or the light receiving use optical fiber on the body surface is performed after completing the actual optical measurement for living body which is for obtaining the living body information inside the living body of the subject, and further comprises means for rejecting a hemoglobin signal for obtaining the living body information inside the living body for a measurement channel of which setting is evaluated inadequate by the optical fiber setting adequacy evaluation unit (Col.10 lines 34-Col.12 line 67, Fig7,8).

With respect to claim 13, Yamashita discloses a method of optical measurement for living body comprising step of irradiating inspection light having a predetermined wavelength of from visible to near infrared range with an irradiation use optical fiber set at an irradiation position on a body surface in an inspection area of a subject (Col. 6 lines 6-17, lines 36-39), step of receiving the inspection light which is irradiated from the adjacent irradiation use optical fiber and penetrated through inside the subject with a light receiving use optical fiber at a light receiving position adjacent the irradiation use optical fiber on the body surface in the inspection area (Col.6 lines 42-51), step of detecting the amount of the inspection light received by the light receiving use optical fiber in a form of

electrical signal (Col.7 lines 30-34), step of calculating a hemoglobin signal representing hemoglobin concentration inside the subject through which the inspection light has penetrated based on the detected electrical signal (Col.8 line 63-Col.9 line 5), step of evaluating setting adequacy on the body surface in the inspection area of the irradiation use optical fiber or the light receiving use optical fiber (Figure 1, Element 17), step of calculating an intensity of a pulse wave component due to heartbeats of the subject contained in the hemoglobin signal calculated on the body surface of the subject of the irradiation use optical fiber or the light receiving use optical fiber based on the intensity of the pulse wave component calculated in the step (Col.8 lines 63-67, Col.9 lines 20-67).

With respect to claims 14-15, the setting adequacy evaluation on the body surface of the irradiation use optical fiber or the light receiving use optical fiber are performed during a preparatory measurement prior to an actual optical measurement for living body which is for obtaining the living body information inside the living body of the subject and a resetting is performed for an irradiation use optical fiber and/or a light receiving use optical fiber of a measurement channel of which setting is evaluated inadequate by the optical fiber setting adequacy evaluation step and step of rejecting after the actual measurement a hemoglobin signal for obtaining living body information inside the living body of a measurement channel for which the resetting of the irradiation use optical fiber or light receiving use optical fiber on the body surface has been performed is

evaluated inadequate regardless to the performance of the resetting of the irradiation use optical fiber and/or light receiving use optical fiber (Col.10 lines 34-Col.12 line 67, Fig7,8).

With respect to claim16, the evaluation of the setting adequacy of the irradiation use optical fiber or the light receiving use optical fiber on the body surface is performed after completing the actual optical measurement for living body which is for obtaining the living body information inside the living body of the subject, and further comprises step of rejecting a hemoglobin signal for obtaining the living body information inside the living body for a measurement channel of which setting is evaluated inadequate by the optical fiber setting adequacy evaluation step(Col.10 lines 34-Col.12 line 67, Fig7,8,9).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 3-7 are rejected under 35 U.S.C. 103(a) as being obvious over Yamashita USPN 6,611,698(cited by applicant) in view of USPN 6,374,128 to Toida et al.

With respect to claims 3/1, 3/2, 4/1, 4/2, Yamashita discloses an optical measurement apparatus for living body comprising all the limitations of claim 1 and 2 such as a measurement channel, a light detection unit, a signal calculation and processing unit.

While Yamashita discloses a signal calculation and processing unit including pulse wave calculation unit which calculates intensity, Yamashita does not specifically disclose a calculating the intensity at the center frequency among the pulse wave component, Which is the fourth order statistics around the center frequency.

Toida teaches a blood vessel imaging system which calculates the intensity of the center frequency among the beat components(Col.4 lines 15-20). It would have been obvious to one with ordinary skill in the art at the time of invention, to modify the pulse wave calculation unit of Yamashita with teachings of Toida, since such modification would have provided the unit with intensity of the center frequency.

With respect to claims 5/1, 5/2, 6, 7, Yamashita discloses an optical measurement apparatus for living body comprising all the limitations of claim 1 and 2 such as a measurement channel, a light detection unit, a signal calculation and processing unit.

While Yamashita discloses a signal calculation and processing unit including pulse wave calculation unit which calculates intensity, Yamashita does not

specifically disclose a pulse wave calculation unit which is provided with means for applying a band pass filter comprising low pass and high pass filter to the remaining of the calculations.

Toida teaches a blood vessel imaging system including a filtering means for filtering the detected signal comprising a low pass and high pass filter, and inputting the filtered signal to rest of the pulse wave calculation unit in order to calculate the intensity of the center frequency(Col.2 lines 8-12 and Col.3 lines 6-28). It would have been obvious to one with ordinary skill in the art at the time of the invention to modify the pulse wave calculation unit of the Yamashita to include a band pass filter as taught by Toida, since such modification would have provided clear signal within the threshold value for further calculations.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJAN FARDANESH whose telephone number is (571)270-5508. The examiner can normally be reached on Monday-Thursday 8:00 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571)272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARJAN FARDANESH/
Examiner, Art Unit 4123

/Derris H Banks/
Supervisory Patent Examiner, Art Unit 3729